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<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		<b>ATTORNEY'S DOCKET NUMBER 24-038-TN</b>
INTERNATIONAL APPLICATION NO. <b>PCT/JP2005/004567</b>	INTERNATIONAL FILING DATE <b>March 15, 2005</b>	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/592953</b>
		PRIORITY DATE CLAIMED <b>March 17, 2004</b>
<b>TITLE OF INVENTION</b> <b>METHOD OF PRODUCING A PHARMACEUTICAL COMPOSITION</b>		
<b>APPLICANT(S) FOR DO/EO/US</b> <b>Eiji NOGAMI</b>		
<p>Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:</p> <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input type="checkbox"/> A preliminary amendment.</li> <li>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> </ol>		

This collection of information is required by 37 CFR 1.414 and 1.491–1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
<b>10/592953</b>	PCT/JP2005/004567	24-038-TN

20. Other items or information:

The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) . . . . . \$300				\$300	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of the PCT Article 33(1)-(4) . . . . . \$0 All other situations . . . . . \$200				\$200	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of the PCT Article 33(1)-(4) . . . . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority . . . . . \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB . . . . . \$400 All other situations . . . . . \$500				\$ 400	
TOTAL OF 21, 22 and 23 =				\$900	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing IN COMPLIANCE WITH 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.				\$ 0	
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
39 -100 =	0 /50 =	0	x \$250	\$ 0	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of the commencement of the national stage (37 CFR 1.492(h)).				\$ 130	
CLAIMS				NUMBER FILED	
Total claims				5 - 20 =	0
Independent claims				1 - 3 =	0
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+	\$360
TOTAL OF ABOVE CALCULATIONS =				\$1390	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					
SUBTOTAL =				\$1390	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+ \$ 0	
TOTAL NATIONAL FEE =				\$1390	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+ \$ 0	
TOTAL FEES ENCLOSED =				\$1390	
				Amount to be refunded:	\$
				Amount to be charged:	\$

10/592953  
IAP9/Rec'd PCT/PTO 15 SEP 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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- a.  A check in the amount of \$ 1390.00 to cover the above fees is enclosed.
- b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1147. A duplicate copy of this sheet is enclosed.
- d.  Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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**IAP9/Rec'd PCT/USPTO 15 SEP 2006**

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PRACTICE LIMITED TO FEDERAL PATENT,  
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\*\* PATENT AGENT

September 15, 2006

**PCT DO/EO/US HAND DELIVERY FILING RECEIPT**

**Applicant(s):** NOGAMI et al.

**For:** METHOD OF PRODUCING A PHARMACEUTICAL COMPOSITION

**Docket:** 24-038-TN

**Attorney:** James E. Barlow

**Date of Deposit:** September 15, 2006

The following documents are being hand delivered to, and deposited with, the USPTO at the DO/EO/US, Mail Stop PCT, Customer Service Window, Randolph Building, 1<sup>st</sup> Floor, 401 Dulany Street, Alexandria, VA 22314 on the above-indicated date, and are addressed to the Commissioner of Patents and Trademarks/Assistant Commissioner for Patents, Mail Stop PCT, Alexandria, VA 22314:

- Return receipt postcard;
- Completed Transmittal Letter Form PTO-1390, including fee calculation sheet;
- 38-page specification including 5 numbered claims;
- 1 sheet of formal drawing [Fig. 1];
- Application data sheet (2 pages); and
- Check for \$1390 for payment of PCT national stage filing fees.